CHILDREN'S HOSPITAL LOS ANGELES
INFORMED CONSENT/PARENTAL PERMISSION/ASSENT TO PARTICIPATE IN A RESEARCH STUDY

Impact of Meal Timing on Glycemic Profile in Latino Adolescents with Obesity: a Pilot Study

Subject's Name:	_____	**Birth Date:**	_____
CHLA MRN#	_____		

A person who takes part in a research study is called a research subject or research participant. If you are reading this consent form as a parent/legal guardian "you" also refers to "your child" (the research participant) and/or the research participant.

KEY INFORMATION

You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide the details of the research.

What should I know about this research?

- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't want to take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask the research team questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

Participation will last up to 2-weeks.

Why is this research being done?

This research is being done to find out how timing of eating impacts body fat, body mass index (BMI) and blood sugar levels after a 16-hour fasting period.

What happens to me if I agree to take part in this research?

Study procedures for this research are:

- You will attend 3 visits at CHLA and have pre-visit phone calls.
  - If there are missing lab results, you will be given the option to redo the visits (up to 6 visits total)
- You will fast for 16 hours before each visit.
- At each visit, you will eat a standard test meal in random order at different times of day:
  - Early: 8 AM, Afternoon: 12 PM and Late: 4 PM
- At each visit, you will have an IV placed (or if you have a port we will use that) for the collection of blood samples before and after the test meal.

- You will be asked to wear a continuous glucose monitor every day for 2 weeks.
- You will have weight and height measured at each visit.
- You will be asked to complete surveys.

Please see the PROCEDURES section below for a complete list of study related procedures.

Could being in the research hurt me?
The most important risks or discomforts that you may expect from taking part in the research are:
- Feeling uncomfortable answering some of the questions.
- Mild discomfort (pain), bruising and swelling where the needle is placed in your arm, and dizziness or fainting from blood draws.
- Headache or dizziness after not eating for prolonged periods during the 16-hour fasting eating period.
- Mild discomfort (pain), bruising or irritation at the insertion site from wearing a continuous glucose monitor.

Please see the POSSIBLE RISKS AND DISCOMFORTS section below for a complete list of expected risks.

Will being in this research benefit me?
The most important benefits that you may expect from taking part in this research are:
- Learning about your health and gaining a better understanding of nutritional strategies.
- Improving glycemic control.

What other choices do I have besides taking part in this research?
Instead of being in this study, your choices may include:
- Get routine care or treatment for your condition.
- Join another clinical research study.

INTRODUCTION
You are invited to join a research study led by Dr. Alaina Vidar, MD from the Endocrinology Department at Children's Hospital Los Angeles (CHLA). This research is paid for by The Southern California Center for Chronic Health Disparities in Latino Children and Families.

You are invited to join this study because you are between 13 and 19 years of age and diagnosed with obesity. Participation in this study is voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to be in the study.

PURPOSE OF THE STUDY
The purpose of this research is to determine how the time at which you eat impacts body fat, body mass index (BMI) and blood sugar levels to a test meal after a 16-hour fasting period.

NUMBER OF PARTICIPANTS
30 adolescents and 30 family members will be asked to take part in this study at CHLA.

LENGTH OF PARTICIPATION
Participation in this research will last 2-weeks with up to 3 in-person study visits at CHLA. If there are missing lab results, you will be given the option to redo the visits (up to 6 visits total)

PROCEDURES
If you volunteer to be in this study, we will ask you to do the following things:

You will eat three standard test meals in random order at different times of day. A computer program will randomly (like flipping a coin) assign you to one of the following times of day to begin your test meal after the first week of wearing a continuous glucose monitor (CGM):
The three test meal times are:
(1) Early: 8 AM **(2)** Afternoon: 12 PM and **(3)** Late: 4 PM

During the research study you will be asked to do the following things (each of these items is specific for the research study and not considered standard of care for your condition):

- **Surveys (visit 1, 2, 3):** You will complete surveys at every visit. These surveys collect information such as demographic information, medical history, and satisfaction with your CGM. Each survey will take approximately 5-10 minutes to complete. You also have the option of completing the surveys virtually via WebEx or over the phone.
- **Weight and height measurement (visits 1, 2, 3):** At every visit, we will weigh you and measure your height. This will be done in a private area.
- **Dietary Recall (visits 1, 2, 3):** You will complete a dietary recall of all the food and beverages you had 1-day prior to the day of each visit. This will take approximately 45 minutes to complete. The dietary recalls will take place virtually via WebEx or over the phone.
- **Medical record review:** If you are a patient at CHLA, as part of your regular care, you may have blood work done every year to evaluate for your health. We will review your medical record and collect the results of your blood work if they occurred in the last 8 weeks from the consent date.
- **Strictly follow the fasting guidelines provided to you by the study team (visits 1,2, 3):**
    - You will be required to strictly fast for 16-hours before each of your study visits.

- **Continuous glucose monitor:** You will wear a continuous glucose monitor called the Dexcom G6 Mobile CGM system every day to monitor your blood sugar level. The study team will create a Dexcom research account on your behalf using a research email. The study team will review your blood sugar levels with you over the phone each week. We will provide you with the device to use for 2-weeks. You will be trained on the use of this device. The Dexcom app will be downloaded to your or family member's personal smart phone. If you or your family member does not own a Dexcom compatible smart phone, you will use the Dexcom receiver. Please see appendix B for information about this device.
- **Pre-visit phone call (visits 1, 2, 3):** A member of the research team will call you before your visit to discuss any barriers you may be experiencing and to record any medication changes or health issues that have occurred in the last 7 days. These conversations should last approximately 15-30 minutes. A code name of your choice can be used during these conversations.
- **Research blood draws & Meal-Test (visits 1, 2, 3):** In preparation for the test, you will eat 16 hours before your test and fast leading up to the test. During the test, you will eat an Early, Afternoon, or Evening meal. You will have an IV placed in your arm (if you do not have a port) and have blood samples drawn 10 minutes before eating the meal, and then at 10, 30, 60, 90, 120, and 180 minutes after eating the meal. Approximately 5 mL (about 1 teaspoon) of blood will be collected per time point (35 mL or 7 teaspoons in total at each visit).

FOR YOUR PARENT/GUARDIAN OR OTHER FAMILY MEMBER

Your participation is optional if your child is over the age of 18 years.

- **Surveys:** Your family member will be asked to complete surveys. These surveys will collect information such as age, job, health insurance, and ethnicity. Each survey will take about 5-10 minutes to complete. You will have the option to complete the surveys at in person visits or virtually via WebEx or over the phone.

Your family member will need to travel to CHLA with you for your in-person study visits and/or to complete in person study procedures.

POSSIBLE RISKS AND DISCOMFORTS

Surveys: You may feel uncomfortable answering some of the questions. You can choose to skip or stop answering questions at any time. Surveys that will be completed by you and your family member ask about demographic and medical history.

Research blood draws: Having an IV inserted to have your blood taken may cause minor discomfort, pain, swelling, bruising, redness, minor bleeding at the site of the IV. In rare cases, an infection may happen.

Prolonged fasting prior to study meal consumption: There are risks and discomforts associated with prolonged fasting, such as thirst, headaches, and gastrointestinal issues. To reduce the risks, you will be encouraged to stay hydrated by drinking water.

Continuous Glucose Monitor: While wearing the Continuous Glucose Monitor, you are at risk for developing pain, bleeding, or burning at the insertion site. In rare cases, an infection may develop.

Progression to diabetes requiring escalation of care: All participants have obesity and thus are at an increased risk of conversion to youth onset type 2 diabetes. If during the study visits any of the biochemical analysis is suggestive of new onset type 2 diabetes, you will be referred to your primary care provider for confirmatory lab testing and referral to a pediatric endocrinologist as needed.

Binge Eating Behavior: If you report unhealthy eating behaviors such as binge eating, excessive restraint and/or purging to a research staff during the research visits, we will refer you to your primary provider to have an official psychological evaluation. If we suspect that you are purging or placing yourself in immediate medical danger, we will contact your parent or guardian and create a safety plan and instruct you to go the local emergency room for evaluation. In addition, the PI will contact the primary care provider to ensure appropriate referrals for psychiatric support are obtained. Adolescents who experience psychiatric emergencies will be withdrawn from the study.

Trauma, Bullying, and Domestic Violence Risks: If we suspect that you are a victim of trauma and/or domestic violence, either through completion of the questionnaires or reported by you, we will implement the following procedures: (1) we will make you aware of resources available to you in your community, such as shelters; (2) we will work with you to develop a safety plan for addressing violence and seeking shelter; and (3) we will ascertain the risk to you. If we suspect that you have been abused or witnessed domestic violence, we will report the incident to child protective services. Children/adolescents who are victims of domestic violence will be allowed to remain in the study if they wish to do so.

Suicidal Behavior Risks: If we suspect that you are suicidal, we will follow the Substance Abuse and Mental Health Services Administration SAFE-T: Suicide Assessment Five-Step Evaluation and Triage approach to determining risk and clinical response. The five steps are Identify Risk Factors, Identify Protective Factors, Conduct Suicide Inquiry, Determine Risk Level/Intervention, and Document (which includes intervention and follow-up). Adolescents who experience psychiatric emergencies such as suicidal behavior will be withdrawn from the study.

As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality may occur. The researchers have procedures in place to lessen the possibility of this happening (see the CONFIDENTIALITY section below for details).

POSSIBLE BENEFITS TO SUBJECTS

You may benefit from participating in this study by:

- Learning about your health and improving glycemic control
- Learning new skills for healthy eating and better understanding of nutritional strategies

POSSIBLE BENEFITS TO SOCIETY
This study will help the researchers learn more about the feasibility, safety, and efficacy of early vs. late Time-Restricting Eating in adolescents with obesity. Hopefully this information will help in the treatment of future patients with obesity.

YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY
The alternative to being in this research is to get the standard of care. The standard of care is to receive care at a multi-disciplinary weight management clinic which includes meeting with several doctors to develop a weight loss program and techniques to help you lose weight and maintain your weight loss. You can also choose not to participate in this study.

COSTS TO YOU FOR BEING IN THIS STUDY
Participants and their families are not responsible for any of the costs involved in this study. The CGM device will be provided to you at no cost while you take part in the study. Neither you nor your insurance company will be billed for your participation in this research. However, participants will continue to be responsible for their phone and service plans.

Parking validation will be provided on an as needed basis, upon request. All families who do not have a car will be offered ride share options (UBER or Lyft) for travel to and from CHLA for the study visits.

If you have questions about your insurance coverage, or the items you might be required to pay for, please discuss them with the study team.

PAYMENT FOR PARTICIPATION
For taking part in this research, you will be paid up to a total of $150. You will be paid as follows:

- You will receive $50 per research visit attended in the form of a gift card.
- You will receive payment for every visit completed. If you leave the study early, you will not get paid for the remaining of the visits.

RESEARCH INJURY
If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The research doctor’s name and phone number are provided in this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer.

CONFIDENTIALITY
The data and specimens (blood samples) collected as part of this study will be “coded.” Coded means that the data and specimens collected for this study will be assigned a unique code or Study ID. Your research data and specimens will not include your name or any other identifying information about you. The code that could be linked back to your

identifying information will be kept separate from your research data and specimens. Only the members of the study team will be able to see the link or the information that can identify you. To manage study data, we will use a secure web application that will be protected with security measures and with coded ID numbers and electronic security systems. Access to your data and biological specimens will be limited only to the study's investigators and clinical support staff for this study.

People on the research team and your doctors and nurses will know that you are in this research study. All results will be kept confidential.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. Your private information, data and medical records will be shared with individuals and organizations that oversee this research, including:

- Government agencies, such as the Department of Health and Human Services.
- The CHLA Institutional Review Board (IRB) that reviewed this research, and authorized representatives of CHLA.

Because this study involves medical procedures, a copy of this consent form will be placed in your medical record. This will allow the doctors that are caring for you to obtain information about any medications and/or procedures you are receiving in the study and treat you appropriately.

We will take steps to keep your personal information private, but we cannot guarantee complete secrecy. All identifiable information about you will be replaced with a unique code or study ID. A list linking the code and your identifiable information will be kept separate from the research data. All research data and records will be stored electronically on a secure network with encryption and password protection to help prevent unauthorized access to your personal information.

We will not release information about you to others not listed above, unless required or permitted by law. For instance:

- if we learn of child or elder abuse, harm to self or others, or
- if you have certain infectious diseases; or
- you are injured and need emergency care.

The results of the research may be presented or published. We will keep your name and other identifying information confidential.

FUTURE RESEARCH USE OF DATA AND SPECIMENS

The data and specimens collected as part of this study will not be used for future research, even if all identifiers are removed.

STUDY WITHDRAWAL

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data/specimens collected about/from you up to that point will remain part of the study and may not be removed from the study database but no more data will be collected.

QUESTIONS ABOUT THE STUDY

If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the CHLA Principal Investigator, Dr. Alaina Vidmar, at 323-361-3385.

Evenings, nights, weekends or holidays you may call the hospital number, (323) 660-2450 and ask for the Endocrinology Service doctor on-call.

This research is being overseen by the CHLA Institutional Review Board ("IRB"). An IRB is a group of people who perform ethical review of research studies. You may talk to them at (323) 361-2265, or hspp@chla.usc.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

ClinicalTrials.gov is a Web site that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time

RIGHTS OF RESEARCH SUBJECTS

You can agree to take part in this study and stop your participation in the study anytime. You should not sign this form if you have any questions that have not been answered or if you are unclear about any information in this form.

Your participation in the study is entirely voluntary. If you choose not to take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know. You are not under any obligation to participate in a research study conducted by your doctor.

You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the research. If this happens, you might be asked to sign a new consent form.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from CHLA.
- If you decide not to take part, you can still receive medical care from CHLA.
- You will be given a copy of this signed and dated consent form and the "Experimental Subject's Bill of Rights" to keep.
- You will be asked to sign a separate CHLA HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information.

SIGNATURE OF RESEARCH SUBJECT
(*For adults who are capable of providing consent; children ages 14 to 17 years old who are capable of providing assent*)

Your signature below indicates:
- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent/assent to your participation in this research study; and
- You will be given a signed copy of this form.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF PARENT(S)/LEGAL GUARDIAN(S)
(*For all subjects under the age of 18*)

Your signature(s) below indicates:
- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You agree to your child's participation in this research study;
- You agree to your own participation in this research study; and
- You will be given a signed copy of this form.

_____ _____
Print Name(s) of Parent(s)/Legal Guardian(s)

_____ _____
Signature of Parent/Legal Guardian Date

_____ _____
Signature of Parent/Legal Guardian Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT
I have explained the research to the subject and/or the subject's parent(s)/legal guardian(s) and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent/permission/assent to participate.

_____
Print Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)
Your signature below indicates:

- You were present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject and/or the subject's parent(s)/legal guardian
- The subject and/or the subject's parent(s)/legal guardian(s) had an opportunity to ask questions and those questions were answered; and
- The subject and/or the subject's parent(s)/legal guardian(s) voluntarily signed the consent/permission/assent form in your presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date

APPENDIX - Schedule of Study Procedures

	Visit 0	Visit 1	Week 2	Visit 3
Study Visit	Consent Visit	Day 3	Day 6	Day 12
Study Window	NA	NA	+ /- 7 days	+ /- 7 days
FOR YOU (the youth)				
**Consent	X			
Randomization	X	X		
Weight and height measured		X	X	X
**CGM Use and Data Review	X	X	X	X
**Surveys		X	X	X
**24-hour Dietary Recall Collection		X	X	X
**Pre-Visit phone call		X	X	X
Research blood draw/fasting labs		X	X	X
Meal Test		X	X	X
FOR YOUR PARENT/GUARDIAN OR FAMILY MEMBER				
**Surveys		X	X	X

**You have the option of completing these procedures virtually via WebEx or over phone. If you opt for this option, you will have to coordinate this with the study team.

APPENDIX B – Continuous Glucose Monitoring Device Use

You and your family member (if under 18 years of age) will be educated in the use of the Dexcom G6 Mobile CGM system during the screening procedures. You will receive training on the system using prepared training materials. All initial sensor insertions will be performed at the clinic by you and/or your family member, under the supervision of the Research Team, using the automated sensor applicator. The applicator measures 65.7 × 115.8 × 49.8 mm (H × W × L) and features a single button that deploys the sensor and retracts the introducer needle when pressed. You will use the G6 system for one 10-day wear period (up to 240 h). Sensors that fail within the first 12 h after insertion will be replaced. This system allows transmission of sensor glucose values via Bluetooth to a mobile device or Dexcom receiver. The Dexcom app will be downloaded to you and/or your family members' personal smart phone using a research account. If you and/or family members do not have a Dexcom compatible smart phone, you will use the Dexcom receiver. Low alert of the CGM on the participant's device will be set at 60 mg/dL. Family members and youth will not be permitted to change alerts during the study. No specific education around trend arrows and alerts will be imparted. You will be instructed to contact the CRC for questions regarding excessive alerts.